

Draft Guidance for Industry
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products
Chemistry, Manufacturing, and Controls Documentation

Docket No. 99D-1454, CDER 98185, June 2, 1999
Page 29657 [FR Doc. 99-13921]

Line 411 - Spray Weight Delivery

In general, pump spray weight delivery acceptance criteria should control the weight of the individual sprays to within ± 15 percent of the target weight and 412 their mean weight to within ± 10 percent of the target weight. 413

For small dosage pumps (e.g. 20 μ l, 25 μ l...), the pump spray weight delivery acceptance criteria may need to be set based on the capabilities of the nasal spray pump as the relative variation of the pump mechanism is greater due to the small dosages being delivered.

99D-1454

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BORDEREAU D'EXPEDITION
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NOM DE L'EXPÉDITEUR / SENDER W. BOLF		N° DE TÉLÉPHONE / TELEPHONE NO. 33-013917-2030	
VALDOIS PHARMACIE ROUTE DES FALAISES			
LE VAUDREUIL			
CODE POSTAL / POSTAL CODE 27100		PAYS / COUNTRY FR	
N° DE COMPTE UPS DU DESTINATAIRE / RECEIVER'S UPS ACCOUNT NO.		N° DE T.V.A. DU DESTINATAIRE RECEIVER'S V.A.T. NO. IDENTIFICATION NO. FOR CUSTOMS PURPOSES	
NOM DU DESTINATAIRE / CONTACT G. Poch, Kian		N° DE TÉLÉPHONE / TELEPHONE NO. (301) 827-1050	
DOCKETS MANAGEMENT BRANCH HFA 305 FOOD AND DRUG ADMINISTRATION 5630 FISHER'S LANE, Rm. 1061			
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ROCKVILLE, MD			
OPTIONS DE FACTURATION / PAYMENT OF CHARGES			
FACTURER LE COMPTE UPS DE L'EXPÉDITEUR Bill Shipper's UPS Account	FACTURER LE DESTINATAIRE Bill Receiver	FACTURER LE COMPTE UPS D'UN TIERCE Bill Third Party UPS Account	Autels Euro/ Master Card Or Visa Autels Euro/ Master Card Or Visa
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F.O.B.		C.A.F.	
<input type="checkbox"/>		<input type="checkbox"/>	
Autels Euro-Plus, Euro Plus Plus		Options Tax Free Options A La Carte Et L'option	
<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Options Clear Plus Tax Exempt		Bill Ship, Tax And Customs Commodities To Be Exempt	
<input type="checkbox"/>		<input type="checkbox"/>	

TYPE DE SERVICE - SER.		
Express Plus	<input type="checkbox"/>	1+
Express	<input checked="" type="checkbox"/>	1
Expedited	<input type="checkbox"/>	2
Standard	<input type="checkbox"/>	

SERVICES EN OPTION / OPTIONAL SERVICES

<input type="checkbox"/>	LIVRAISON LE SAMEDI SATURDAY DELIVERY
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INSTRUCTIONS SPECIALES / SPECIAL INSTRUCTIONS

JCS

RENSEIGNEMENTS CONCERNANT L'ENVOI		SHIPMENT INFORMATION
NOMBRE DE COUS PACKAGES IN SHIPMENT 1	POIDS TOTAL REEL TOTAL ACTUAL WEIGHT kg	POIDS TOTAL VOLUMETRIQUE TOTAL DIMENSIONAL WEIGHT kg
<input checked="" type="checkbox"/> UPS EXPRESS ENVELOPE		

DATE D'EXPEDITION DATE OF SHIPMENT	SIGNATURE DE L'EXPÉDITEUR SHIPPER'S SIGNATURE
JJ MM AA 27 08 99	W. B. S.

REFERENCE N° 1 / REFERENCE N° 1	
ERD	
REFERENCE N° 2 / REFERENCE N° 2	
DESCRIPTION DES MARCHANDISES / DESCRIPTION OF GOODS	DOCUMENTS SEULEMENT / DOCUMENTS ONLY
Documents	<input checked="" type="checkbox"/>
COCHER SI LES MARCHANDISES NE SONT PAS EN LIBRE CIRCULATION DANS L'UNION EUROPÉENNE	<input type="checkbox"/> GOODS NOT IN FREE CIRCULATION IN THE UK



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